WHAT IS CLAIMED IS:

1. A method to stimulate reversal of a diabetic state in a patient, which comprises *in vivo* inducing re-growth of new insulin-producing cells by administering a therapeutically effective amount of a pro-neogenesis factor to said patient, wherein formation of mature islets of Langerhans is indicative of a stimulated reversal of a diabetic state.

2. The method of claim 1, wherein said pro-neogenesis factor is selected from the group consisting of growth factors, GLP-1, exendin-4, and an INGAP peptide.

3. The method of claim 2, wherein said growth factor is selected from the group consisting of insulin, IGF-I, IGF-II, EGF, Gastrin and NGF.

4. The method of claim 1, wherein said insulin-producing cells are pancreatic beta-cells.

5. A method to prevent autoimmune destruction of new insulin-producing cells (pancreatic beta-cells) in a patient, which comprises administering to said patient a therapeutically effective amount of at least one immunosuppressive agent in combination with an INGAP peptide.

6. The method of claim 5, wherein said immunosuppressive agent is selected from the group consisting of sirolimus, tacrolimus, and a combination thereof.

7. A method to promote survival of the newly regenerated insulin-producing cells, which comprises administering a pro-neogenesis factor in a therapeutically effective amount to a patient.

8. The method of claim 7, wherein said pro-neogenesis factor is selected from the group consisting of growth factors, GLP-1, exendin-4, and an INGAP peptide.

9. The method of claim 8, wherein said growth factor is selected from the group consisting of insulin, IGF-I, IGF-II, EGF, Gastrin and NGF.

10. The method of claim 8, wherein said insulin-producing cells are pancreatic beta-cells.

11. An *in vivo* method for the induction of islet cell neogenesis and new islet formation and the prevention of autoimmune destruction of said new cells, which comprises the steps of:

a) administering INGAP peptide to said patient in an amount sufficient to stimulate transformation of putative islet cell stem/progenitor cells in adult pancreas into islet hormone-producing cells under normal endogenous homeostatic control mechanisms, whereby cells expand in number and develop a mature glucose-sensing mechanism in a regulated manner;

b) concurrently administering to said patient at least one immunosuppressive agent in an amount sufficient to protect said islet cells from immune destruction; and

c) concurrently administering a pro-survival factor to said patient during islet cell neogenesis and new islet formation.

12. The method of claim 11, wherein said islet hormone-producing cells are pancreatic beta-cells.

13. The method of claim 12, wherein said immunosuppressive agent is selected from the group consisting of sirolimus, tacrolimus, and a combination thereof.

14. The method of claim 11, wherein said pro-survival factor is selected from the group consisting of insulin, IGF-I, IGF-II, EGF and NGF.

15. An *in vivo* method for the induction of islet cell neogenesis and new islet formation and the prevention of autoimmune destruction of said new cells, which comprises the steps of:

a) administering INGAP peptide to said patient in an amount sufficient to stimulate transformation of putative islet cell stem/progenitor cells in adult pancreas into islet hormone-producing cells under normal endogenous homeostatic control mechanisms, whereby cells expand in number and develop a mature glucose-sensing mechanism in a regulated manner;
b) concurrently administering a pro-survival factor to said patient during islet cell neogenesis and new islet formation.

16. The method of claim 15, wherein said islet hormone-producing cells are pancreatic beta-cells.

17. The method of claim 15, wherein said pro-survival factor is selected from the group consisting of insulin, IGF-I and IGF-II.

18. A pharmaceutical composition for the preparation of a medicament to stimulate reversal of a diabetic state in a patient by *in vivo* inducing re-growth of new insulin-producing cells, which comprises a therapeutically effective amount of a pro-neogenesis factor in association with a pharmaceutically acceptable carrier.

19. The pharmaceutical composition of claim 18, wherein said pro-neogenesis factor is selected from the group consisting of growth factors, GLP-1, exendin-4, and an INGAP peptide.

20. The pharmaceutical composition of claim 18, wherein said growth factor is selected from the group consisting of insulin, IGF-I, IGF-II, EGF, Gastrin and NGF.

21. A pharmaceutical composition for the preparation of a medicament to prevent autoimmune destruction of new insulin-producing cells in a patient, which comprises a therapeutically effective amount of at least one immunosuppressive agent and an INGAP peptide factor in association with a pharmaceutically acceptable carrier.

22. The pharmaceutical composition of claim 21, wherein said immunosuppressive agent is selected from the group consisting of sirolimus, tacrolimus, and a combination thereof.

23. A pharmaceutical composition for the preparation of a medicament to promote survival of the newly regenerated insulin-producing cells, which comprises a therapeutically effective amount of a pro-neogenesis factor in association with a pharmaceutically acceptable carrier.

24. The pharmaceutical composition of claim 23, wherein said pro-neogenesis factor is selected from the group consisting of growth factors, GLP-1, exendin-4, and an INGAP peptide.

25. The pharmaceutical composition of claim 24, wherein said growth factor is selected from the group consisting of insulin, IGF-I, IGF-II, EGF, Gastrin and NGF.

26. The pharmaceutical composition of claim 23, wherein said insulin-producing cells are pancreatic beta-cells.

27. A pharmaceutical composition for the preparation of a medicament for the induction of islet cell neogenesis and new islet formation and the prevention of autoimmune destruction of said new cells, which comprises an INGAP peptide in an amount sufficient to stimulate transformation of putative islet cell stem/progenitor cells in adult pancreas into islet hormone-producing cells under normal endogenous homeostatic control mechanisms; at least one immunosuppressive agent in an amount sufficient to protect said islet cells from immune destruction; and a pro-survival factor in association with a pharmaceutically acceptable carrier.

28. The pharmaceutical composition of claim 27, wherein said islet hormone-producing cells are pancreatic beta-cells.

29. The pharmaceutical composition of claim 27, wherein said immunosuppressive agent is selected from the group consisting of sirolimus, tacrolimus, and a combination thereof.

30. The pharmaceutical composition of claim 29, wherein said pro-survival factor is selected from the group consisting of insulin, IGF-I, IGF-II, EGF and NGF.

31. A pharmaceutical composition for the preparation of a medicament for the induction of islet cell neogenesis and new islet formation and the prevention of autoimmune destruction of said new cells, which comprises an INGAP peptide in an amount sufficient to stimulate transformation of putative islet cell stem/progenitor cells in adult pancreas into islet hormone-producing cells under normal endogenous homeostatic control mechanisms; and a pro-survival factor in association with a pharmaceutically acceptable carrier.

32. The pharmaceutical composition of claim 31, wherein said islet hormone-producing cells are pancreatic beta-cells.

33. The pharmaceutical composition of claim 31, wherein said pro-survival factor is selected from the group consisting of insulin, IGF-I, IGF-II, EGF, and NGF.

34. Use of a therapeutically effective amount of a pro-neogenesis factor to stimulate reversal of a diabetic state in a patient, wherein formation of mature islets of Langerhans is indicative of a stimulated reversal of a diabetic state.

35. The use of claim 34, wherein said pro-neogenesis factor is selected from the group consisting of growth factors, GLP-1, exendin-4, and an INGAP peptide.

36. The use of claim 35, wherein said growth factor is selected from the group consisting of insulin, IGF-I, IGF-II, EGF, Gastrin and NGF.

37. Use of a therapeutically effective amount of at least one immunosuppressive agent in combination with an INGAP peptide to prevent autoimmune destruction of new insulin-producing cells in a patient.

38. The use of claim 37, wherein said immunosuppressive agent is selected from the group consisting of sirolimus, tacrolimus, and a combination thereof.

39. Use of a therapeutically effective amount of a pro-neogenesis factor to promote survival of the newly regenerated insulin-producing cells.

40. The use of claim 39, wherein said pro-neogenesis factor is selected from the group consisting of growth factors, GLP-1, exendin-4, and an INGAP peptide.

41. The use of claim 40, wherein said growth factor is selected from the group consisting of insulin, IGF-I, IGF-II, EGF, Gastrin and NGF.

42. The use of claim 39, wherein said insulin-producing cells are pancreatic beta-cells.

43. Use of an INGAP peptide in an amount sufficient to stimulate transformation of putative islet cell stem/progenitor cells in adult pancreas into islet hormone-producing cells under normal endogenous homeostatic control mechanisms; at least one immunosuppressive agent in an amount sufficient to protect said islet cells from immune destruction; and a pro-survival factor for the induction of islet cell neogenesis and new islet formation and the prevention of autoimmune destruction of said new cells in a patient.

44. The use of claim 43, wherein said islet hormone-producing cells are pancreatic beta-cells.

45. The use of claim 43, wherein said immunosuppressive agent is selected from the group consisting of sirolimus, tacrolimus, and a combination thereof.

46. The use of claim 43, wherein said pro-survival factor is selected from the group consisting of insulin, IGF-I, IGF-II, EGF and NGF.

47. Use of an INGAP peptide in an amount sufficient to stimulate transformation of putative islet cell stem/progenitor cells in adult pancreas into islet hormone-producing cells under normal endogenous homeostatic control mechanisms; and a pro-survival factor for the induction of islet cell neogenesis and new islet formation and the prevention of autoimmune destruction of said new cells in a patient.

48. The use of claim 47, wherein said islet hormone-producing cells are pancreatic beta-cells.

49. The use of claim 47, wherein said pro-survival factor is selected from the group consisting of insulin, IGF-I, IGF-II, EGF and NGF.